ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoules of 1000, 2000 and 4000 doses of vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac MD Rispens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

MDV

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 D
2000 D
4000 D

(on the tag)

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot: {number}

(on the tag)

7. EXPIRY DATE

EXP:

Store: -196°C

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Ceva-Phylaxia Co. Ltd.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE DILUENT

Solvent bag, 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml

1. NAME OF THE DILUENT

Cevac Solvent Poultry

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

200 ml
400 ml
800 ml
1000 ml
1200 ml
1600 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25°C.
Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company logo

or

Ceva-Phylaxia Co. Ltd.
1107 Budapest
Szállás u 5.

Hungary

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Cevac MD Rispens concentrate and solvent for suspension for injection for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Limited
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release
CEVA-Phylaxia Co. Ltd.
1107 Budapest
Szállás u 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac MD Rispens concentrate and solvent for suspension for injection for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose (0.2 ml) contains:

Active substance:
Cell-associated live Marek's disease virus (MDV)
serotype 1, strain CVI-988 800-5000 PFU*
*PFU: plaque forming unit

Concentrate: yellow to reddish brown, dense, frozen virus suspension.
Solvent: clear, orange to red solution.

4. INDICATION(S)

For active immunisation of one-day-old future layer chicks to reduce mortality, clinical signs and lesions caused by very virulent strains of Marek's disease virus.

Onset of immunity: 9 days after vaccination.

Duration of immunity: A single vaccination is sufficient to provide protection during the risk period of infection with Marek's disease virus.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use (preferably under the skin of the neck):
One single injection of 0.2 ml per chick is applied at one day of age.
The vaccine may be injected by automatic syringe. Overview table for recommended dilution possibilities of different presentations:

Cevac MD Rispens No. of ampoules x doses (D)	**Solvent presentation (ml)**	**Volume of one dose (ml)**
1 x 1,000 D	200	0.20
1 x 2,000 D	400	
2 x 2,000 D	800	
1 x 4,000 D	800	
4000 + 1000 D	1000	
3 x 2000 D	1200	
2 x 4000 D	1600	

Overview table for recommended dilution possibilities of different presentations in case of associated use:

No. of ampoules x doses (D)		**Solvent presentation (ml)**	**Volume of one dose (ml)**
Cevac MD Rispens	**Vectormune ND**		
1 x 1,000 D	1 x 1,000 D	200	0.20
1 x 2,000 D	1 x 2,000 D	400	
2 x 2,000 D	2 x 2,000 D	800	
1 x 4,000 D	1 x 4,000 D	800	
4000 + 1000 D	4000 + 1000 D	1000	
3 x 2000 D	3 x 2000 D	1200	
2 x 4000 D	2 x 4000 D	1600	

9. ADVICE ON CORRECT ADMINISTRATION

The usual aseptic precautions should be applied to all administration procedures.

Be familiar with all safety and precautionary measures for handling liquid nitrogen in order to prevent personal injury.

Reconstitution of the vaccine:

1. Use *Cevac Solvent Poultry* for reconstitution. After matching the dose size of the ampoules with the solvent size, quickly remove the exact number of ampoules needed from the liquid nitrogen container.
2. Draw up 2 ml of solvent into a 5 ml syringe. Use minimum 18 gauge needle. In case of associated use different syringe should be used for each vaccine.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39°C.
4. As soon as they are completely thawed, open ampoules holding them at arm length in order to prevent any risk of injury should the ampoule break.
5. Once the ampoule is open, slowly draw up the content into the 5-ml sterile syringe prepared as in point 2.
6. Transfer the thawed suspension into the solvent bag. The reconstituted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine from the solvent bag into the syringe and use it to rinse the ampoule. Inject it gently back into the solvent bag. Repeat once or twice.
8. The reconstituted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2-7 for the appropriate number of ampoules to be thawed.
Use the reconstituted vaccine immediately, slowly mix regularly to ensure uniform suspension of cells and use within a period not exceeding 2 hours.

It should be ensured that the diluted vaccine is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine remains homogenous and that the correct virus titer is administered during vaccination session.

Do not use Cevac MD Rispens if you notice visible signs of unacceptable decolourisation in the vials.
Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Do not re-use opened containers of diluted vaccine.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Concentrate:
Store and transport frozen in liquid nitrogen (-196°C).

The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed. Store liquid nitrogen container securely in upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room in the hatchery.

Solvent:
Store below 25°C. Do not freeze.

Shelf life after reconstitution according to directions: 2 hours at a temperature below 25°C.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

Spread of the vaccine strain was demonstrated between chickens and may occur from 14 days after vaccination. Vaccinated chickens may excrete the vaccine strain for at least 112 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.
The excreted vaccine strain is safe in non-vaccinated chickens.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

Special precautions should be taken to avoid spreading of the vaccine strain to quails and pheasants.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Liquid nitrogen containers and vaccine ampoules should be handled by properly trained personnel only.
Personal protective equipment consisting of protective gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.
Frozen glass ampoules may explode during sudden temperature changes.
Store and use liquid nitrogen in a dry and well-ventilated place only. Inhalation of the liquid nitrogen vapour is dangerous.
Personnel attending vaccinated birds should follow hygiene principles and take particular care in handling litter from vaccinated chickens.

Lay: Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Vectormune ND by subcutaneous application.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
No symptoms were observed after the administration of a 10-fold overdose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except Vectormune ND (where it is marketed) and solvent recommended for use with the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Concentrate:
One Type I glass ampoule containing 1000, 2000 or 4000 doses.
The ampoules are put on canes with tag and stored in a liquid nitrogen container.

Solvent:
Polyvinylchloride bag containing 200, 400, 800 , 1000, 1200 or 1600 ml in individual over-pouch.

Not all pack sizes may be marketed.

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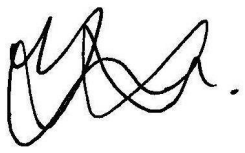

Approved: 26 September 2022